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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,104	09/22/2003	Thomas Ho	T9666.NP.CIP	7629
28122 7590 01/16/2007 THORPE NORTH & WESTERN P.O. BOX 1219 SANDY, UT 84091-1219			EXAMINER SHEIKH, HUMERA N	
			ART UNIT	PAPER NUMBER
			1615	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/16/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/668,104	HO, THOMAS	
	<b>Examiner</b>	<b>Art Unit</b>	
	Humera N. Sheikh	1615	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 March 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                        |                                                                   |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/5/04; 3/21/05</u> .                                         | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### Status of the Application

Receipt of the Information Disclosure Statements (IDS) filed 01/05/04 and 03/21/05 and the Change of Address Notice filed 12/27/04 is acknowledged.

Claims 1-22 are pending in this action. Claims 1-22 are rejected.

### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,630,166 B1 ('166 Patent) in view of Hsiao *et al.* – U.S. Patent No. 6,346,269 B1 ('269 Patent).

The instant claims are drawn to a pharmaceutical composition in a solid oral dosage form comprising: a core containing a therapeutically effective amount of at least one conjugated estrogen, or a component thereof, and at least one organic excipient, wherein the at least one organic excipient comprises less than about 25% w/w of a cellulose ingredient, and less than about 50% w/w of a sugar ingredient, and at least one inorganic excipient, wherein the at least one inorganic excipient includes a calcium phosphate tribasic ingredient in an amount of less than about 20% w/w; and a pharmaceutically acceptable coating that is free of hormones, wherein the composition does not crack when stored at 40°C and 75% relative humidity for about two months.

The issued claims of the '166 Patent are also drawn to a pharmaceutical composition in a solid oral dosage form comprising: a core containing a therapeutically effective amount of at least one conjugated estrogen, or a component thereof, and at least one organic excipient, wherein the at least one organic excipient comprises less than about 25% w/w of a cellulose ingredient, and less than about 50% w/w of a sugar ingredient, and at least one inorganic excipient, wherein the at least one inorganic excipient comprises a calcium phosphate tribasic ingredient and a pharmaceutically acceptable coating that is free of hormones, wherein the composition does not crack when stored at 40°C and 75% relative humidity for about two months.

The only distinction observed between the instant claims and the '166 Patent is that the instant claims in independent claim 1 recites the amount of inorganic excipient - tribasic calcium phosphate to be in an amount of less than about 20% w/w; whereas in the '166 Patent,

independent claims 1, 6 and 9 are silent as to any required amounts of the excipient - tribasic calcium phosphate. Dependent claims 2-5, 7, 8, 10 and 11 of the '166 Patent are also silent as to any amounts of tribasic calcium phosphate.

The Examiner points out that suitable amounts of excipient can be determined by one of ordinary skill in the art through the use of routine or manipulative experimentation to obtain optimal results.

The secondary reference of Hsiao *et al.* ('269) is relied upon to demonstrate that the use of calcium phosphate tribasic as an art-recognized excipient in active ingredient formulations is well known (see Claim 21 of '269).

Therefore, it would have been obvious to one of ordinary skill in the art to incorporate the excipient calcium phosphate tribasic as taught by Hsiao *et al.* because they teach that calcium phosphate tribasic is a suitable and effective excipient that is routinely employed in formulations comprising active agents.

### **Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Art Unit: 1615


Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Humera N. Sheikh

Primary Examiner

Art Unit 1615

January 06, 2007

  
HUMERA N SHEIKH  
PRIMARY EXAMINER  
TC-1600

*hns*